



# Use of Symbols on Medical Device Labeling

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*FDA Public Workshop:*  
Accessible Medical Device Labeling  
in a Standard Content and Format

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# Food, Drug and Cosmetic Act (2008)

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- **Section 502**

A drug or device shall be deemed to be misbranded –  
–(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness... **and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use....**

# 21 CFR 801, Labeling (2012)

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- **Sec. 801.15, Medical devices;  
prominence of required label statements**  
(c) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling **shall appear thereon in the English language....**

# Current FDA Exceptions (1 of 2)

Symbol	Used for	Symbol	Used for
	Do not reuse		Use by YYYY-MM-DD or YYYY-MM
	Batch code		Serial number
	Date of manufacture		Sterile
	Sterilized using ethylene oxide		Sterilized using irradiation
	Sterilized using steam or dry heat		Catalog number
	Caution, consult accompanying documents		Sterilized using aseptic processing technique
	Manufacturer		Authorized representative in the European Community
	Contains sufficient for < n > tests		For IVD Performance Evaluation only
	In vitro diagnostic medical device		Upper limit of temperature
	Lower limit of temperature		Temperature limitation
	Consult instructions for use		Biological risks
	Control		Negative control
	Positive control	Graphic symbols for use in labeling	

- **OIVD Guidance Document (2004)**
  - Allows “use of [24] selected symbols in place of text to convey some of the information required for in vitro diagnostic devices (IVDs) intended for professional use by 21 CFR 809.10... and 21 CFR parts 610 and 660....”

# Current FDA Exceptions (2 of 2)

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- **Rx Guidance Document (2000)**

- FDA “...does not intend to object to the use of the statement **‘Rx only’** as an alternative to the prescription device labeling statement “Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).”

“Only” needs to immediately follow “Rx.” However, the symbol statement “Rx only” does not necessarily need to be bracketed in quotation marks, and the word “only” may appear in upper or lower case letters, for example, Rx only, Rx Only, or Rx ONLY.

# FDA Plans for Symbols

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- **FDA plans to allow use of symbols without adjacent text on labeling of more types of medical devices**
  - Revise affected sections of **regulation**
  - Develop new **guidance document**
    - Will supersede the two current guidance documents
  - Update FDA's **standards recognitions** to identify which standardized symbols will be allowed on which types of medical devices

# News for Symbols

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- **Draft regulation published Friday, April 19**
- **FDA 2013-N-0125**
- **Recognizes certain symbols in FDA recognized standards without adjacent text**
- **Must still have a glossary explaining the symbol's meaning**

# Contact Information

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